K000658

MAY 11 2000

DePuy
a Johnson & Johnson company

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46581-0988
510(K) CONTACT:	Lynnette Whitaker Group Leader, Regulatory Affairs
TRADE NAME:	ERS Radial Head Replacement
COMMON NAME:	Radial Head Replacement
CLASSIFICATION:	888. 3170 Elbow Joint Radial (Hemi-elbow) Polymer Prosthesis
DEVICE PRODUCT CODE:	Product code: 87 KWI
SUBSTANTIALLY EQUIVALENT DEVICES:	-Pritchard Elbow Resurfacing System with Porocoat®, DePuy -Modular Radial Head, Wright Medical Technology, Inc. -Radial Head Surface Replacement, Implex Corp. -Radial Head Implant, Avanta Orthopaedics, Inc.

DEVICE DESCRIPTION AND INTENDED USE:
The ERS Radial Head Replacement System consists of a modular porous coated stem and a bearing that articulates with the humerus. The ERS Radial Head Replacement System is indicated for:

- The replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with:
  - -Joint destruction and/or subluxation visible on x-ray
  - -Resistance to conservative treatment
- Primary replacement after fracture of the radial head
- Symptomatic sequelae after radial head resection
- Revision following failed radial head arthroplasty.

BASIS OF SUBSTANTIAL EQUIVALENCE:
The components of the ERS Radial Replacement are identical to components cleared by FDA for total elbow arthoplasty indications, and are similar in design to currently marketed radial replacement systems for identical indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2000

Ms. Lynnette Whitaker
Group Leader, Regulatory Affairs
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K000658
Trade Name: ERS Radial Head Replacement System
Regulatory Class: II
Product Code: KWI
Dated: February 24, 2000
Received: February 28, 2000

Dear Ms. Whitaker:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lechner for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K00-0658

Device Name ERS Radial Head Replacement System

Indications for Use:

The ERS Radial Head Replacement System is indicated for:

- The replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with:
  - -Joint destruction and/or subluxation visible on x-ray
  - -Resistance to conservative treatment
- Primary replacement after fracture of the radial head
- Symptomatic sequelae after radial head resection
- Revision following failed radial head arthroplasty

Concurrence of CDRH, Office of Device Evaluation

Donna R. Bachman

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000658

Prescription Use √ OR (Per 21 CFR 801.109) Over-The Counter Use ____